

What is claimed is:

1. A method, for evaluating a biological condition of a subject, comprising:
  - a. obtaining from the subject a sample having at least one of RNAs and proteins;
  - 5 b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and
  - 10 c. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject.
- 15 2. A method, for evaluating a biological condition of a subject, comprising:
  - a. obtaining from the subject a first sample having at least one of fluid, cells and active agents;
  - b. applying the first sample or a portion thereof to a defined
  - 20 population of indicator cells;
  - c. obtaining from the indicator cells a second sample containing at least one of RNAs or proteins;
  - d. deriving from the second sample a first profile data set, the first profile data set including a plurality of members, each member being a quantitative
  - 25 measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and
  - e. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the
  - 30 first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject.
3. A method, for evaluating a biological condition affected by an agent, the

method comprising:

- a. obtaining, from a target population of cells to which the agent has been administered, a sample having at least one of RNAs and proteins;
  - b. deriving from the sample a first profile data set, the first profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and
  - c. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition as affected by the agent.
4. A method according to any of claims 1 through 2, wherein the baseline profile data set is derived from one or more other samples from the same subject taken under conditions different from those of the sample.
5. A method according to claim 4, wherein the conditions are selected from the group consisting of (i) the time at which a given sample is taken, (ii) the site from which a given sample is taken, (iii) the physiological condition of the subject when a given sample is taken.
6. A method according to claim 4, wherein the one or more other samples are taken over an interval of time that is at least twelve months between an initial sample and the sample.
7. A method according to claim 4, wherein the one or more other samples are taken over an interval of time that is at least one month between an initial sample and the sample.
8. A method according to any of claims 1 through 3, wherein the sample is derived from blood and the baseline profile data set is derived from tissue or body fluid of the subject other than blood.

9. A method according to claim 4, wherein the baseline profile data set is derived from one or more other samples from the same subject, taken when the subject is in a physiological condition different from that in which the subject was at the time the sample was taken, with respect to at least one of age, diet, medication, and environmental exposure.

10. A method according to claim 3, wherein the baseline profile data set is derived from one or more other samples from the same population taken under conditions different from those of the sample.

11. A method according to claim 10, wherein the conditions are selected from the group consisting of (i) the time at which a given sample is taken and (ii) the physiological condition of the population when a given sample is taken.

12. A method according to claim 10, wherein the one or more other samples are taken over an interval of time that is at least twelve months between an initial sample and the sample.

13. A method according to claim 10, wherein the one or more other samples are taken over an interval of time that is at least one month between an initial sample and the sample.

14. A method according to claim 10, wherein the sample is derived from blood and the baseline profile data set is derived from tissue or body fluid of the subject other than blood.

15. A method according to claim 10, wherein the baseline profile data set is derived from one or more other samples of cell populations associated with a common subject, the populations taken when the subject is in a physiological condition different from that in which the subject was at the time the sample was taken, with respect to at least one of age, diet, medication, and environmental exposure.

16. A method according to any of claims 1 and 2, wherein the baseline profile

data set is derived from one or more other samples from one or more different subjects.

17. A method according to claim 16, wherein the one or more different subjects have in common with the subject at least one of age group, gender, ethnicity, geographic location, diet, medical disorder, clinical indicator, medication, physical activity, body mass, and environmental exposure.

18. A method according to claim 3, wherein the baseline profile data set is derived from one or more other samples from one or more cell populations associated with different subjects.

19. A method according to claim 18, wherein the one or more different subjects have in common with the subject at least one of age group, gender, ethnicity, geographic location, diet, medical disorder, clinical indicator, medication, physical activity, body mass, and environmental exposure.

20. A method according to any of claims 1 through 3, further comprising: interpreting the calibrated profile data set in the context of at least one other clinical indicator.

21. A method according to claim 20, wherein the indicator is selected from the group consisting of blood chemistry, urinalysis, X-ray, other chemical assays, and physical findings.

22. A method according to any of claims 1 through 3, wherein the biological condition is a complex disease process, involving multiple genes, the disease being of a type involving at least one of inflammation, auto-immune disease, degenerative disease, allergy, vascular disease, ischemia, cancer, developmental disease, hormonal condition, aging and infectious diseases.

23. A method according to claim 22, wherein the biological condition is one of arthritis, asthma, multiple sclerosis, and perimenopausal change.

24. A method according to any of claims 1 and 2, wherein the subject is a

living organism.

25. A method according to claim 24, wherein the subject is a mammal.

5 26. A method according to claim 3, wherein the population of cells is human cells.

27. A method according to claim 3, wherein the population of cells is mammalian cells.

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28. A method according to any of claims 1 through 3, wherein the sample is derived from one or more of body fluid and tissue.

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29. A method according to any of claims 1 through 3, wherein the sample is derived from blood.

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30. A method according to any of claims 1 through 3, wherein the sample is derived from one of a biopsy, a needle aspirate, a lavage specimen, a scraping, and a surgical specimen.

31. A method according to any of claims 1 through 3, wherein the sample is derived from tissue or fluid of a type distinct from that with respect to which the condition is clinically manifested.

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32. A method according to any of claims 1 through 3, wherein the condition is a disease and the sample is derived from tissue or fluid of a type distinct from that which is a primary target of the disease.

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33. A method according to any of claims 1 through 3, wherein the function is other than a simple difference.

34. A method according to claim 33, wherein the function is a second function of the ratio of the corresponding member of first profile data set to the corresponding member of the baseline profile data set.

35. A method according to claim 34, wherein the function is a logarithmic function.

5 36. A method according to any of claims 1 through 3, wherein each member of the calibrated profile data set is reproducible with respect to similar samples taken from the subject under similar conditions.

10 37. A method according to any of claims 1 through 3, wherein each member of the calibrated profile data set is reproducible within one order of magnitude with respect to similar samples taken from the subject under similar conditions.

15 38. A method according to any of claims 1 through 3, wherein each member of the calibrated profile data set is reproducible within fifty percent with respect to similar samples taken from the subject under similar conditions.

20 39. A method according to any of claims 1 through 3, wherein each member of the calibrated profile data set is reproducible within twenty percent with respect to similar samples taken from the subject under similar conditions.

40. A method according to claim 34, wherein each member of the calibrated profile data set is reproducible within one order of magnitude with respect to similar samples taken from the subject under similar conditions.

25 41. A method according to claim 34, wherein each member of the calibrated profile data set is reproducible within fifty percent with respect to similar samples taken from the subject under similar conditions.

30 42. A method according to claim 34, wherein each member of the calibrated profile data set is reproducible within twenty percent with respect to similar samples taken from the subject under similar conditions.

43. A method according to claim 34, wherein each member of the calibrated profile data set has biological significance if it has a value differing by more than an

amount D, where  $D = F(1.1) - F(.9)$ , and F is the second function.

5 44. A method according to any of claims 1 through 3, wherein the biological condition concerns an organ and the panel of constituents enables measurement of the condition in relation to the organ.

10 45. A method according to any of claims 1 and 2, wherein the biological condition concerns a system of the subject, the system selected from the group consisting of respiratory, vascular, nervous, metabolic, urinary, reproductive, structural, and immunological systems, and the panel of constituents enables measurement of the condition of the subject in relation to the system.

15 46. A method according to claim 3, wherein the population of cells is derived from a subject and the biological condition concerns a system of the subject, the system selected from the group consisting of respiratory, vascular, nervous, metabolic, urinary, reproductive, structural, and immunological systems, and the panel of constituents enables measurement of the condition of the subject in relation to the system.

20 47. A method according to claim 46 and the panel includes at least half of the constituents of the Inflammation Precision Panel.

48. A method according to claim 46 and the panel includes at least eighty percent of the constituents of the Inflammation Precision Panel.

25 49. A method according to claim 46 and the panel includes at least half of the constituents of the Cell Growth and Differentiation Precision Panel.

30 50. A method according to claim 46 and the panel includes at least eighty percent of the constituents of the Cell Growth and Differentiation Precision Panel.

51. A method according to claim 46 and the panel includes at least half of the constituents of a Metabolism and Toxicity Precision Panel.

52. A method according to claim 46 and the panel includes at least eighty

percent of the constituents of a Metabolism and Toxicity Precision Panel.

53. A method according to any of claims 1 through 3, wherein the number of constituents in the panel is at least three but less than 100.

54. A method according to any of claims 1 through 3, wherein the number of constituents in the panel is at least four but less than 100.

55. A method according to any of claims 1 through 3, wherein the number of constituents in the panel is at least at least five but less than 100.

56. A method according to any of claims 1 through 3, wherein the number of constituents in the panel is at least is at least six.

57. A method according to claim 3, wherein the agent is selected from the group consisting of a drug, a mixture of compounds, a functional food, a nutraceutical, a therapeutic agent, an allergen, and a toxin.

58. A method according to any of claims 1 through 3, wherein deriving the first profile data set from the sample includes hybridizing the sample with a set of nucleic acid probes.

59. A method according to claim 58, wherein the probes are attached to an insoluble matrix and the sample is applied to the matrix.

60. A method according to claim 3, wherein evaluating the condition affected by the agent includes evaluating the interaction of the agent with a second agent administered to the population of cells.

61. A method according to claim 60, wherein the interaction is neutral.

62. A method according to claim 60, wherein the interaction is interference.

63. A method according to claim 60, wherein the interaction is cumulative.



64. A method according to claim 60, wherein the interaction is synergistic.

65. A method according to claim 60, wherein the agent is a pharmaceutical.

5 66. A method, for evaluating the effect on a biological condition by a first agent in relation to the effect by a second agent, the method comprising:

- 10 a. obtaining, from first and second target populations of cells to which the first and second agents have been respectively administered, first and second samples respectively, each sample having at least one of RNAs and proteins;
- b. deriving from the first sample a first profile data set and from the second sample a second profile data set, the profile data sets each including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the
- 15 constituents enables measurement of the biological condition; and
- c. producing for the panel a first calibrated profile data set and a second profile data set, wherein (i) each member of the first calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a first baseline profile data set for the panel, and (ii) each member of the
- 20 second calibrated profile data set is a function of a corresponding member of the second profile data set and a corresponding member of a second baseline profile data set for the panel, the calibrated profile data sets providing a measure of the effect by the first agent on the biological condition in relation to the effect by the second agent.

25 67. A method according to claim 66, wherein the first agent is a drug and the second agent is a complex mixture.

68. A method according to claim 66, wherein the first agent is a drug and the second agent is a nutraceutical.

30 69. A method according to any of claims 1 through 3, wherein obtaining the sample and quantifying the first profile data set are performed at a first location, and producing the calibrated profile data set includes using a network to access a database stored on a digital storage medium in a second location.

70. A method according to claim 69, further comprising updating the database to reflect the first profile data set quantified from the sample.

5 71. A method according to claim 69, wherein using a network includes accessing a global computer network.

72. A method of conducting a clinical trial of an agent, the method comprising:

- 10 a. causing the blind administration of a selected one of a placebo and the agent to each candidate of a pool of subjects; and
- b. using quantitative gene expression to monitor an effect of such administration.

15 73. A method according to claim 72, wherein the pool of subjects is selected using quantitative gene expression analysis on a plurality of candidates to identify those candidates likely to show a response to the agent.

20 74. A method according to claim 72, wherein the administration includes determining at least one of a dosage and a dosage range by using quantitative gene expression analysis.

25 75. A method according to claim 72, further comprising using quantitative gene expression analysis to assist in determining at least one of efficacy and toxicity of the agent.

30 76. A method according to any of claims 72 through 75, wherein using quantitative gene expression analysis includes using the method of at least one of claims 1, 2, and 3.

77. A digital storage medium on which is stored a computer readable calibrated profile data set, wherein:

a. the calibrated profile data set relates to a sample having at least one of RNAs and proteins derived from a target cell population to which an agent has been

administered; and

b. the calibrated profile data set includes a first plurality of members, each member being a quantitative measure of a change in an amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of a biological condition as affected by administration of the agent.

78. A digital storage medium according to claim 77, wherein: (i) each member of the calibrated profile data set is a function of a corresponding member of a post-administration data set and a corresponding member of a baseline data set; (ii) each member of the baseline data set is a quantitative measure of the amount of a distinct RNA or protein constituent in the panel under a normative condition; and (iii) each member of the post-administration data set is a quantitative measure of the amount of a distinct RNA or protein constituent in the panel under a condition following administration of the agent to the target cell population.

79. A medium according to claim 78, wherein the function is a second function of the ratio of the corresponding member of baseline data set to the corresponding member of the post-administration data set.

80. A medium according to claim 79, wherein the second function is a logarithmic function.

81. A digital storage medium according to any of claims 77-80, wherein the agent is a pharmaceutical.

82. A digital storage medium according to any of claims 77-80, wherein the agent includes a second plurality of components.

83. A digital storage medium according to any of claims 77-80, wherein the agent is a nutraceutical.

84. A digital storage medium according to any of claims 77-80, wherein the first plurality is at least three but less than 1000.

85. A digital storage medium according to any of claims 77-80, wherein the first plurality is at least four but less than 1000.

5 86. A digital storage medium according to any of claims 77-80, wherein the first plurality is at least five but less than 1000.

87. A digital storage medium according to any of claims 77-80, wherein the first plurality is at least six.

10 88. A digital storage medium on which is stored a plurality of records  $R_i$  relating to a population of subjects, each record  $R_i$  corresponding to a distinct instance  $P_i$  of a computer readable profile data set  $P$  wherein:

15 a. each instance  $P_i$  of the profile data set  $P$  relates to a distinct sample derived from a subject, the sample having at least one of RNAs and proteins;

b. the profile data  $P$  set includes a plurality of members  $M_j$ , each member  $M_j$  being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of a biological condition;

20 c. each record  $R_i$  includes, for each member  $M_{ij}$  of a corresponding distinct instance  $P_i$  of the profile data set  $P$ , a value corresponding to the value of the member  $M_{ij}$ ; and

25 d. each record  $R_i$  also includes a reference to a characteristic of the subject relative to the record, the characteristic being at least one of age group, gender, ethnicity, geographic location, diet, medical disorder, clinical indicator, medication, physical activity, body mass, and environmental exposure.

30 89. A digital storage medium according to claim 88, wherein each sample is derived from a target cell population to which has been administered an agent, such target cell population being derived from a subject.

90. A digital storage medium on is stored a large number of computer readable profile data sets, wherein:

a. each profile data set relates to a sample derived from a target cell

population to which has been administered an agent, the sample having at least one of RNAs and proteins;

- b. each profile data set includes a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of a biological condition; and
- c. the panel is the same for all profile data sets.

91. A method, for evaluating a biological condition of a subject, based on a sample from the subject, the sample having at least one of RNAs and proteins, the method comprising:

- a. deriving from the sample a first instance of a profile data set, the profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

- b. producing a first instance of a calibrated profile data set for the panel, wherein each member of an instance of the calibrated profile data set is a function of a corresponding member of an instance of the profile data set and a corresponding member of an instance of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject; and

- c. accessing a data in a condition database, the condition database having a plurality of records relating to a population of subjects, each record corresponding to a distinct instance of the calibrated profile data set; and

- d. evaluating the first instance of the calibrated profile data set in relation to data in the condition database.

92. A method according to claim 91, wherein accessing the condition database includes accessing the condition database over a network.

93. A method according to claim 92, wherein the network is a global computer network.

94. A method according to claim 92, further comprising supplementing the

condition database based on data associated with the first instance of the calibrated profile data set.

95. A method according to claim 92, wherein the biological condition concerns a system of the subject, the system selected from the group consisting of respiratory, vascular, nervous, metabolic, urinary, reproductive, structural, and immunological systems and the panel of constituents enables measurement of the condition of the subject in relation to the system.

96. A method according to claim 92, wherein each record also references a characteristic of the population relative to the record, the characteristic being at least one of age group, gender, ethnicity, geographic location, diet, medical disorder, clinical indicator, medication, physical activity, body mass, and environmental exposure.

97. A method according to claim 96, wherein the characteristic includes a clinical indicator.

98. A method of displaying quantitative gene expression analysis data associated with measurement of a biological condition, the method comprising:

a. identifying a first profile data set pertinent to the gene expression analysis data, the first profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition;

b. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject; and

c. displaying the calibrated profile data set in a graphical format.

99. A method according to claim 98, wherein the function is a second function of the ratio of the corresponding member of first profile data set to the corresponding member of the baseline profile data set.

100. A method according to claim 97, wherein the function is a logarithmic function.

5 101. A method according to claim 97, wherein the graphical format is a bar graph for each member of the calibrated profile data set.

102. A descriptive record of a change in a biological condition in a population of cells, comprising:

10 a. a first set of numerical gene expression values for a panel of gene loci, each value in the set corresponding to a single gene locus in a panel of gene loci, the set of values forming a profile data set for a population of cells subjected to a first biological condition;

15 b. a second set of numerical gene expression values for the panel of gene loci, each value in the set corresponding to a single gene locus, the set of values forming a baseline profile data set for a second population of cells subjected to a second biological condition, the second set of values optionally being an average for multiple gene expression values from multiple populations of cells for each locus in the panel; and

20 c. a third set of numbers corresponding to the ratio of the first set of values and the second set of values with respect to each gene locus in the panel, the third set being a calibrated profile data set; the profile data set and the calibrated profile data set being descriptive of the first biological condition with respect to the second biological condition.

25 103. A record according to claim 102, wherein the first population of cells and the second or more population of cells are the same population of cells.

104. A record according to claim 102, wherein the first population of cells and the second or more population of cells are different populations of cells.

30 105. A descriptive record, according to claim 102, wherein a sample is obtained from a subject, for subjecting the cells to a biological condition, the cell population being an indicator cell population.

106. A gene expression profile data set, according to claim 102, wherein the population of cells is in a subject or derived from a subject.

107. A method for diagnosing a biological condition of a subject, comprising:  
5 obtaining a sample from a subject; subjecting a population of cells to the sample and determining the presence of a first biological condition with respect to a second biological condition according to any of claims 1 through 3.

108. A method according to claim 107, further comprising: selecting the  
10 subject for a clinical trial according to the biological condition of the subject, so as to determine predictively whether the subject will respond to a test compound if the compound has a predetermined biological activity.

109. A method according to claim 108, wherein the test compound is a  
15 pharmaceutical agent.

110. A method according to claim 108 where the test compound is a nutraceutical agent.

111. A method for diagnosing a susceptibility for a biological condition in a  
20 subject, comprising:  
a. obtaining a sample from the subject;  
b. creating a descriptive record, according to any of claims 102 through 106, wherein the set of baseline values is an average of second values contained  
25 in a library of baseline profile data sets for the second biological condition; the library containing a plurality of baseline profile data sets grouped according to a predetermined biological condition; and  
c. diagnosing the susceptibility of the subject.

112. A method for monitoring the progress of a biological condition,  
30 comprising:  
a. creating a plurality of descriptive records, according to any of claims 102 through 106, wherein each set of first values is determined at preselected time intervals with respect to each of the other gene expression profiles;



b. comparing each calibrated profile data set with a library of calibrated profile data sets, the plurality of calibrated profile data sets being grouped according to a predetermined biological condition; and

c. determining the progress of the biological condition.

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113. A method for establishing a descriptive record for an agent comprising:

a. selecting a population of cells;

b. subjecting the cells to the agent; and

c. determining the record according to any of claims 102 through 106

10 using a standardized baseline profile data set for the biological condition.

114. A method according to claim 113, wherein the composition is a nutraceutical.

15 115. A method according to claim 113, wherein the composition is a pharmaceutical.

116. A method according to claim 113, wherein the composition is an infectious agent.

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117. A method according to claim 113, wherein the composition is a complex mixture.

25 118. A method according to claim 113, wherein establishing the biological activity of the composition further includes providing a mechanism of action for the composition.

30 119. A method according to claim 113, wherein establishing the biological activity of the composition further includes providing a mechanism for metabolism for the composition.

120. A method according to claim 113, wherein the composition further comprises a first compound and a second compound and the biological activity results from any of synergism, interference or neutral interaction between the first and second

compound.

121. A method according to claim 113, wherein the compound further comprises a plurality of compounds such that the biological activity results from any of synergism, interference or neutral interaction between the compounds.

122. A method according to claim 113, wherein the biological activity of the compound is a toxic effect on the subject.

123. A method of selecting a therapeutic agent from a class of therapeutic agents for administering to a subject so as to change a biological condition in a subject from a first biological condition to a second biological condition; comprising:

- a. subjecting a sample from the subject to each of the class of therapeutic agents;
- b. determining a descriptive record for each of the samples according to any of claims 102 through 106;
- c. comparing each of the calibrated profile data sets to a library of calibrated profile data sets; wherein the library of calibrated profile data sets are grouped according to a predetermined biological condition; and
- d. determining which of the therapeutic agents is capable of changing the first biological condition in the subject to the second biological condition in the subject.

124. A method according to claim 122, wherein the first biological condition is a consequence of the adverse effects of any of an infectious agent, a biological warfare agent or an environmental agent and the second biological condition is a reversal of these adverse effects.

125. A method according to claim 122, wherein the library of descriptive records comprise a medical history for a single subject or single condition.

126. A method according to claim 122, wherein the library of descriptive records comprise medical information about a plurality of subjects or conditions.

127. A method according to claim 122, wherein the library of signature profile data sets consist of signature profile data sets from a plurality of subjects.

128. A method for characterizing the biological effectiveness of a single batch of a composition produced by a manufacturing process, comprising:

(a) providing a calibrated data profile set according to the method of claim 3; and labeling the batch of the composition by placing the calibrated data profile set on each container in the batch optionally including the signature calibrated profile data set;

(b) comparing the calibrated profiled data set with a standardized calibrated profile data set.

129. A method for accessing biological information on a digital storage medium according to claim 88, comprising making the information available to a user.

130. A method according to claim 129, wherein the method further comprises making the information available to the user on any of a network, World Wide Web, email, internet access site or hard copy.

131. A method according to claim 128, wherein the method further comprises accessing the information for loading to a second access site.

132. A method according to claim 131, wherein the process for loading includes downloading the information.

133. A method according to claim 129, wherein access to the information is controlled.

134. A method according to claim 133, wherein the process of control includes the use of a password.

135. A method according to claim 129, wherein the user can annotate the available information, the annotation becoming part of the biological information.

136. A method according to claim 129, wherein the user can add one or more records to the data set, the one or more records becoming part of the biological information.

5 137. A method for consumer evaluation of a product, wherein the consumer evaluation is dependent on a signature profile comprising:

(a) forming a descriptive record according to claim 102;  
(b) identifying the product using a descriptive record, wherein the panel of gene loci is a signature panel; and

10 (c) comparing the calibrated profiled data set with an average calibrated profile data set to provide an explanation of the product.

138. A method according to claim 137, wherein the product is promoted according to the signature profile.

15 139. A computer program product for evaluating a biological condition of a subject or for evaluating a biological condition resulting from the use of an agent, including a computer usable medium having computer readable program code thereon, the computer program code; comprising:

20 a. a program code for classifying a sample from the subject or the agent for an identifiable record;

b. a program code for deriving a first data set, the first profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; the profile data set being stored in the record; and

25 c. a program code for optionally producing a calibrated profile data set for the panel, for storage in the record, each member of the calibrated profile data set being a function of a corresponding member of the first profile data set and a  
30 corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject.

140. A computer system for evaluating a biological condition of a subject or for evaluating a biological condition resulting from the use of an agent, the computer system,

comprising:

- a. a classification module for classifying a sample from the subject or the agent in an identifiable record;
- b. a derivative module for deriving a first data set, the first profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and
- c. a production module for producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject.

141. A method for analyzing a patient for a biological condition at a remote site, comprising:

- a. providing a kit for measuring a profile data base for evaluating a biological condition, the kit including reagents for quantitative analysis of RNA or protein for a panel of gene loci;
- b. accessing a centralized database containing baseline profile data sets corresponding to the panel;
- c. determining the calibrated profile data set for the patient; and
- d. analyzing the biological condition of the patient with respect to a library of calibrated profile data sets.

142. A method, for evaluating a biological condition of a subject, comprising:

- d. obtaining from the subject a sample having at least one of RNAs and proteins;
- e. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and
- f. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the

panel, the calibrated profile data set providing a measure of the biological condition of the subject;

wherein the biological condition relates to inflammation and the panel includes at least half of the constituents of the Inflammation Precision Panel of Table 1.

5        143. A method according to claim 142, wherein the panel includes at least eighty percent of the constituents of the Inflammation Precision Panel of Table 1.

144. A method, for evaluating a biological condition of a subject, comprising:

a. obtaining from the subject a sample having at least one of RNAs and proteins;

10        b. deriving from the sample a first profile data set, the first profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

c. producing a calibrated profile data set for the panel, wherein each member  
15 of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject;

wherein the biological condition relates to cell growth and differentiation  
20 and the panel includes at least half of the constituents of the Cell Growth and Differentiation Precision Panel of Table 2.

145. A method according to claim 144, wherein the panel includes at least eighty percent of the constituents of the Cell Growth and Differentiation Precision Panel of Table 2.

25        146. A method, for evaluating a biological condition of a subject, comprising:

a. obtaining from the subject a sample having at least one of RNAs and proteins;

b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the  
30 amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

c. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel,

the calibrated profile data set providing a measure of the biological condition of the subject;

wherein the biological condition relates to metabolism and toxicity and the panel includes at least half of the constituents of the Liver Metabolism and Toxicity

5 Precision Panel of Table 3.

147. A method according to claim 146, wherein the panel includes at least eighty percent of the constituents of the Metabolism and Toxicity Precision Panel of Table 3.

148. A method, for evaluating a biological condition of a subject, comprising:

10 a. obtaining from the subject a sample having at least one of RNAs and proteins;

b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

15 c. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject;

20 wherein the biological condition relates to skin response and the panel includes at least half of the constituents of the Skin Response Precision Panel.

149. A method according to claim 148, wherein the panel includes at least eighty percent of the constituents of the Skin Response Precision Panel of Table 4.

25 150. A method, for evaluating a biological condition of a subject, comprising:

a. obtaining from the subject a sample having at least one of RNAs and proteins;

b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

30 c. producing a calibrated profile data set for the panel, wherein each member of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel,

the calibrated profile data set providing a measure of the biological condition of the subject;

wherein the biological condition relates to the vascular system and the panel includes at least half of the constituents of the Vascular Precision Panel of Table 6.

5        151. A method according to claim 150, wherein the panel includes at least eighty percent of the constituents of the Vascular Precision Panel of Table 6.

152. A method, for evaluating a biological condition of a subject, comprising:

a. obtaining from the subject a sample having at least one of RNAs and proteins;

10        b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

c. producing a calibrated profile data set for the panel, wherein each member  
15 of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject;

wherein the biological condition relates to the prostate health and disease and the  
20 panel includes at least half of the constituents of the Prostate Precision Panel of Table 5.

153. A method according to claim 152, wherein the panel includes at least eighty percent of the constituents of the Prostate Precision Panel of Table 5.

154. A method, for evaluating a biological condition of a subject, comprising:

a. obtaining from the subject a sample having at least one of RNAs and  
25 proteins;

b. deriving from the sample a first profile data set, the first profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition; and

c. producing a calibrated profile data set for the panel, wherein each member  
30 of the calibrated profile data set is a function of a corresponding member of the first profile data set and a corresponding member of a baseline profile data set for the panel, the calibrated profile data set providing a measure of the biological condition of the subject;



wherein the biological condition relates to the prostate health and disease and the panel includes at least half of the constituents of the Prostate Precision Panel of Table 7.

155. A method according to claim 152, wherein the panel includes at least eighty percent of the constituents of the Prostate Precision Panel of Table 7.

- 5 156. A method, for evaluating a biological condition of a subject, comprising:
- a. obtaining from the subject a sample having at least one of RNAs and proteins;
  - b. deriving from the sample a profile data set, the profile dataset including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition;
- 10

wherein such measure is performed for each constituent under conditions wherein efficiencies of amplification for all constituents are substantially similar, the profile data set providing a measure of the biological condition of the subject.

- 15 157. A method according to claim 156, wherein the efficiencies of amplification of all constituents differ by less than approximately 2%.

158. A method, for evaluating a biological condition of a subject, comprising:
- a. obtaining from the subject a first sample having at least one of fluid, cells and active agents;
  - b. applying the first sample or a portion thereof to a defined population of indicator cells;
  - c. obtaining from the indicator cells a second sample containing at least one of RNAs or proteins;
  - d. deriving from the second sample a profile data set, the profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition;
- 20
- 25

wherein such measure is performed for each constituent under conditions wherein efficiencies of amplification for all constituents are substantially similar, the profile data set providing a measure of the biological condition of the subject.

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159 A method according to claim 158, wherein the efficiencies of amplification of all constituents differ by less than approximately 2%.

160. A method, for evaluating a biological condition affected by an agent, the method comprising:

a. obtaining, from a target population of cells to which the agent has been administered, a sample having at least one of RNAs and proteins;

b. deriving from the sample a profile data set, the profile data set including a plurality of members, each member being a quantitative measure of the amount of a distinct RNA or protein constituent in a panel of constituents selected so that measurement of the constituents enables measurement of the biological condition;

wherein such measure is performed for each constituent under conditions wherein efficiencies of amplification for all constituents are substantially similar, the profile data set providing a measure of the biological condition as affected by the agent.

10 161. A method according to claim 160, wherein the efficiencies of amplification of all constituents differ by less than approximately 2%.

162. A method according to any of claims 156, 158, and 160, wherein the panel includes at least four constituents selected from the group consisting of expression products of TNF- $\alpha$ , IL-1- $\alpha$ , IL- $\beta$ , IFN- $\gamma$ , IL-8, and IL-10.

15 163. A method according to any of claims 156, 158, and 160, wherein the panel includes at least four constituents selected from any one of Tables 1 through 7.

164. A kit of primer-probe combinations for measuring expression products of at least four constituents selected from any one of Tables 1 through 7.

20 165. A kit according to claim 164, wherein each primer probe combination is constructed so as to hybridize only to at least one of cDNA and mRNA at a biologically relevant locus.

25 166. A kit according to claim 164, wherein in each combination a reverse primer is complementary to a coding DNA strand located across an intron-exon junction, with not more than three bases of a three-prime end of the reverse primer being complementary to a proximal exon.

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